REMARKS

The Office Action and the cited and applied references have been carefully reviewed. No claim is allowed. Claims 1, 3-10, 12, 13, 27 and 28 presently appear in this application and define patentable subject matter warranting their allowance. Reconsideration and allowance are hereby respectfully solicited.

Claims 14-26 have been rejected under 35 U.S.C. §101 and §112, second paragraph. These two rejections are obviated by the cancellation of claims 14-26.

Reconsideration and withdrawal of the §101 and §112, second paragraph, rejections are therefore respectfully requested.

Claims 1-5, 11-18 and 24-26 have been rejected under 35 U.S.C. §112, first paragraph, as containing subject matter, "FGRF3 inhibitor" and "FGRR3", that encompass a potentially vast array of molecules which are not adequately described in the specification. This rejection is respectfully traversed.

The term "FGFR" (fibroblast growth factor receptor) is well defined at page 10, last paragraph, of the specification as originally filed (i.e., WO 2004/110487) and includes two known isoforms of the receptors, FGFR3IIIc and FGFR3IIIb. New claim 27 is directed to an FGFR3 encoded by the nucleotide sequence of SEQ ID NO:76, as supported in the specification at page 26, lines 4-5 and new claim 28 is directed to the preferred FGFR3IIIb

embodiment, as supported in the specification in the paragraph bridging pages 25 and 26. Furthermore, the present specification provides a large number of examples of FGFR3 inhibitors including specific molecules comprising the antigen-binding portion of an antibody with specific affinity for FGFR3 (see Tables 1 and 2 and pages 13-15 of the present specification).

In order to advance prosecution and also without prejudice, claim 1 is amended to specifically recite that the FGFR3 inhibitor comprises the antigen-binding portion of an antibody that has a specific affinity for FGFR3, which applicant believes is adequately described in the present specification.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 1, 2, 11, 14, 15 and 24-26 have been rejected under 35 U.S.C. §102(b) as being anticipated by Yayon et al., WO 00/27379. This rejection is obviated by the amendments to the claims.

WO 00/27379 discloses porphyrin compounds and derivatives able to inhibit growth factor receptor tyrosine kinase (RTK) activity. As presently recited in claim 1, the FGFR3 inhibitor comprises the antigen-binding portion of an antibody which has a specific affinity to FGFR3. Such an FGFR3 inhibitor is not disclosed in WO 00/27379, and therefore WO 00/27379 cannot anticipate the presently claimed invention.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 1-12 and 14-26 have been rejected under 35 U.S.C. §102(e) or §102(a) as being anticipated by Yayon et al., WO 02/102973. This rejection is respectfully traversed.

WO 02/102973 discloses antibodies to receptor tyrosine kinases and antibodies against FGFR3. WO 02/102973 teaches that the antibodies are used to treat or inhibit diseases associated with proliferative disorders and that "According to the principles of the present invention … including certain skeletal disorders, **hyperproliferative diseases or disorders** and non-neoplastic angiogenic pathologic conditions such as neovascular glaucoma, macular degeneration, hemangiomas, angiofibromas, **psoriasis**" (see page 7, lines 15-21, emphasis added). Thus, according to WO 02/102973, psoriasis is considered a hyperproliferative disease and claim 27 therein is directed to treating and inhibiting **hyperproliferative diseases that are non-neoplastic angiogenic pathologic conditions** such as hemangiomas, angiofibromas and psoriasis (see page 66, Claim 29, emphasis added).

By contrast, the present invention is based on the unexpected finding that inhibition of FGFR3 results in the inhibition and treatment of T cell mediated inflammatory autoimmune diseases. The present invention emphasizes treatment

of diseases affected by the T cells of the immune system as opposed to WO 02/102973, which discloses treatment against hyperproliferative effects.

Claim 1 is amended to recite the proviso that the disease to be treated or inhibited is not psoriasis. As stated in MPEP 2173.01, such a negative limitation is permitted:

> A fundamental principle contained in **35 U.S.C. 112**, second paragraph is that applicants are their own lexicographers. They can define in the claims what they regard as their invention essentially in whatever terms they choose so long as **>any special meaning assigned to a term is clearly set forth in the specification. See MPEP § **2111.01.**< Applicant may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought. As noted by the court in *In re Swinehart*, 439 F.2d 210, 160 USPQ 226 (CCPA 1971), a claim may not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought. (emphasis added)

MPEP 2173.05(i) on Negative Limitations further states:

> The current view of the courts is that there is nothing inherently ambiguous or uncertain about a negative limitation. So long as the boundaries of the patent protection sought are set forth definitely, albeit negatively, the claim complies with the requirements of **35 U.S.C. 112**, second paragraph. Some older cases were critical of negative limitations because they tended to define the invention in terms of what it was not, rather than pointing out the invention. Thus, the court observed that the limitation "R is an alkenyl radical other than 2-butenyl and 2,4-

> pentadienyl" was a negative limitation that rendered the claim indefinite because it was an attempt to claim the invention by excluding what the inventors did not invent rather than distinctly and particularly pointing out what they did invent. *In re Schechter*, 205 F.2d 185, 98 USPQ 144 (CCPA 1953).
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> A claim which recited the limitation "said homopolymer being free from the proteins, soaps, resins, and sugars present in natural Hevea rubber" in order to exclude the characteristics of the prior art product, was considered definite because each recited limitation was definite. *In re Wakefield*, 422 F.2d 897, 899, 904, 164 USPQ 636, 638, 641 (CCPA 1970). In addition, the court found that the negative limitation "incapable of forming a dye with said oxidized developing agent" was definite because the boundaries of the patent protection sought were clear. *In re Barr*, 444 F.2d 588, 170 USPQ 330 (CCPA 1971).
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> Any negative limitation or exclusionary proviso must have basis in the original disclosure. <u>If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims</u>. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ("[the] specification, having described the whole, necessarily described the part remaining."). See also *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984). (emphasis added)

The decision in *In re Johnson* 194 USPQ 196 (CCPA 1977), which is what is currently accepted by the courts and the USPTO, states:

> The notion that one who fully discloses, and teaches those skilled in the art how to make and use, a genus and numerous species therewithin, has somehow failed to disclose,

> and teach those skilled in the art how to make and use, that genus minus two of those species, and has thus failed to satisfy the requirements of §112, first paragraph, appears to result from a hypertechnical application of legalistic prose relating to that provision of the statute. All that happened here is that appellants narrowed their claims to avoid having them read on a lost interference count.
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> The board indicated that "it is manifestly immaterial" *why* appellants limited their claims. Though it is true that insufficiency under §112 could not be cured by citing the causes for such insufficiency, it is not true that the factual context out of which the question under §112 arises is immaterial. Quite the contrary. Here, as we hold on the facts of this case, the "written description" in the 1963 specification supported the claims in the absence of the limitation, and that specification, having described the whole, necessarily described the part remaining. The facts of the prosecution are properly presented and relied on, under these circumstances, to indicate that appellants are merely excising the invention of another, to which they are not entitled, and are not creating an "artificial subgenus" or claiming "new matter." (emphasis added)

In short, the positive recitation in the present specification of psoriasis indeed provides adequate written description to excise what applicants are not entitled to from their claimed invention by the use of negative limitations. Such negative limitations, which have basis in the original disclosure only as positive recitations, are permitted.

Accordingly, WO 02/102973 cannot anticipate the presently claimed invention.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their allowance. Favorable consideration and early allowance are earnestly urged.

Respectfully submitted,

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